UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,280	09/29/2003	Richard A. Schomburg	117163. 00091	3122

21324 7590 05/22/2007

HAHN LOESER & PARKS, LLP
One GOJO Plaza
Suite 300
AKRON, OH 44311-1076

EXAMINER	
CHANG, SUNRAY	
ART UNIT	**PAPER NUMBER**
2121	

NOTIFICATION DATE	DELIVERY MODE
05/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	10/674,280	SCHOMBURG, RICHARD A.	
	Examiner	Art Unit	
	Sunray Chang	2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in responsive to the paper filed on March 13th, 2007.

Claims 1 – 16 are presented for examination.

Claims 1 – 16 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. **Claims 1 – 8 and 10 – 15 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Esteller et al. (U.S. Patent No. 6,594,524, and referred to as **Esteller** hereinafter), and in view of Gabriel Mouchawar et al. (U.S. Patent No. 6,009,349 and referred to as **Mouchawar** hereinafter).

(**Esteller** as set forth above generally discloses the basic inventions.)

Regarding independent claim 1,

Esteller teaches,

An apparatus for the classification of physiological events on the basis of physiological signals (see Abstract, lines 4-10), said apparatus comprising:

a probabilistic neural network (see Brief Description of Drawing Figure 32) which is adapted to receive a set of values representing the physiological signal and which contains a number of event classes which represent physiological events and which are respectively determined by a number of comparative values (see col. 9, lines 48-52), which network is adapted on the basis of the comparison of the set of values with the comparative values to implement an association of the physiological signal represented by the set of values with one of the event classes (see col. 36, lines 51-67 and also see col. 37, lines 1-36)

an updating unit connected to the probabilistic neural network for updating the comparative values of an event class on the basis of the set of values of at least one physiological signal which has been associated with said event class in a preceding association operation. [FIG. 2 illustrates the scheme of the multi-level control, ... The main goal of the multi-level control is to keep the patient from having seizures despite environmental and physiological load disturbances. ... a supervisory control is implemented providing (a) continuous regulation of the controlled variables, (b) adaptation to external or internal changes over time, and (c) a knowledge base used to accomplish the regulation and adaptation by incorporating information as it arises, and updating the system settings and parameters appropriately. [Col. 6, lines 8 – 20; Fig. 2]

Esteller teaches physiological events and physiological signals as indicated above;

Mouchawar teaches cardiac events on the basis of cardiac signals, IEGM (intracardial electrograms) are known to be physiological signals [Arterial blood pressure is a physiologic parameter that is known to be representative of hemodynamic performance, Col. 4, lines 13 – 15; the cardiac wall displacement signals correlate to known hemodynamic indicators, and are shown to be strongly suggestive of hemodynamic performance, Abstract], for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18]

Mouchawar further teaches a signal preparation unit for IEGM [the microprocessor be programmed via the telemetry circuit to operate … to response to either processing system or the IEGM sensing circuit, detail see Col. 10, lines 21 – 51]

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of **Esteller** to include "cardiac events on the basis of cardiac signals, IEGM and a signal preparation unit for IEGM", for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18].

Regarding dependent claim 2, Esteller teaches, the apparatus of claim 1, wherein:

the updating unit is so designed that upon updating of the comparative values an average value is formed from a number of value sets which have previously resulted in an association of the physiological signals which they represent with the event class to be updated and wherein the updating operation is effected on the basis of the average value formed in that way. (see col. 21, Average Power or Moving Average Power)

Mouchawar teaches cardiac events on the basis of cardiac signals, IEGM (intracardial electrograms) are known to be physiological signals [Arterial blood pressure is a physiologic parameter that is known to be representative of hemodynamic performance, Col. 4, lines 13 – 15; the cardiac wall displacement signals correlate to known hemodynamic indicators, and are shown to be strongly suggestive of hemodynamic performance, Abstract], for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18]

Regarding dependent claim 3, Esteller teaches, the apparatus of claim 1 wherein:

the updating unit is so designed that upon updating of the comparative values exponential weighting of a number of value sets which have previously resulted in an association of the physiological signals which they represent with the event class to be updated is effected and wherein the updating operation is effected on the basis of the exponentially weighted value sets. (see col. 23, Average Nonlinear Energy or Moving Average Nonlinear Energy, more specifically col. 24, lines 3-26)

Mouchawar teaches cardiac events on the basis of cardiac signals, IEGM (intracardial electrograms) are known to be physiological signals [Arterial blood pressure is a physiologic parameter that is known to be representative of hemodynamic performance, Col. 4, lines 13 – 15; the cardiac wall displacement signals correlate to known hemodynamic indicators, and are shown to be strongly suggestive of hemodynamic performance, Abstract], for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18]

Regarding dependent claim 4, Esteller teaches, the apparatus of claim 3 wherein:

the updating unit is so designed that updating of an event class is effected after the association of a n-th value set with said event class, wherein that defines a predetermined number of value sets. (see col. 24, Thresholded Nonlinear Energy, lines 27-47)

Regarding dependent claim 5, Esteller teaches, the apparatus of claim 4 wherein:

different values for n are to be associated with different event classes. (see col. 31, Window Length Selection, lines 52-56)

Regarding dependent claim 6, Esteller teaches, the apparatus of claim 5, further comprising:

a signal input for the input of a physiological signal; (see Abstract, lines 4-10) and

a transformation unit (see Figure 3, element 200) which is connected to the signal input for receiving the physiological signal and which is adapted to implement a transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation operation; (see col. 18, lines 41-60 and also see col. 20, lines 26-36) wherein

the probabilistic neural network is connected to the transformation unit for receiving the values as the value set. (see Figure 1, element 200)

Mouchawar teaches cardiac events on the basis of cardiac signals, IEGM (intracardial electrograms) are known to be physiological signals [Arterial blood pressure is a physiologic

parameter that is known to be representative of hemodynamic performance, Col. 4, lines 13 – 15; the cardiac wall displacement signals correlate to known hemodynamic indicators, and are shown to be strongly suggestive of hemodynamic performance, Abstract], for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18]

Regarding dependent claim 7, Esteller teaches, the apparatus of claim 6, wherein:

the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets. (see col. 28, lines 21-44)

Regarding independent claim 8, Esteller teaches,

An implantable medical device (see col. 3, lines 4-7), comprising:

an apparatus for the classification of physiological events on the basis of physiological signals (see Abstract, lines 4-10) comprising:

a probabilistic neural network (see Brief Description of Drawing Figure 32) which is adapted to receive a set of values representing the physiological signal and which contains a number of event classes which represent physiological events and which are respectively determined by a number of comparative values (see col. 9, lines 48-52), which network is adapted on the basis of the comparison of the set of values with the comparative values to implement an association of the physiological signal represented by the set of values with one of the event classes (see col. 36, lines 51-67 and also see col. 37 lines 1-36)

an updating unit connected to the probabilistic neural network for updating the comparative values of an event class on the basis of the set of values of at least one physiological signal which has been associated with said event class in a preceding association operation. [FIG. 2 illustrates the scheme of the multi-level control, ... The main goal of the multi-level control is to keep the patient from having seizures despite environmental and physiological load disturbances. ... a supervisory control is implemented providing (a) continuous regulation of the controlled variables, (b) adaptation to external or internal changes over time, and (c) a knowledge base used to accomplish the regulation and adaptation by incorporating information as it arises, and updating the system settings and parameters appropriately. [Col. 6, lines 8 – 20; Fig. 2]

Esteller teaches physiological events and physiological signals as indicated above;

Mouchawar teaches cardiac events on the basis of cardiac signals, IEGM (intracardial electrograms) are known to be physiological signals [Arterial blood pressure is a physiologic parameter that is known to be representative of hemodynamic performance, Col. 4, lines 13 – 15; the cardiac wall displacement signals correlate to known hemodynamic indicators, and are shown to be strongly suggestive of hemodynamic performance, Abstract], for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18]

Regarding dependent claim 10, Esteller teaches, the apparatus of claim 1, wherein:

the updating unit is so designed that updating of an event class is effected after the association of a n-th value set with said event class, wherein that defines a predetermined number of value sets. (see col. 24, Thresholded Nonlinear Energy, lines 27-47)

Regarding Claim 11, Esteller discloses:

Regarding dependent claim 11, Esteller teaches, the apparatus of claim 2, wherein:

the updating unit is so designed that updating of an event class is effected after the association of a n-th value set with said event class, wherein that defines a predetermined number of value sets. (see col. 24, Duration of Thresholded Nonlinear Energy, lines 27-47)

Regarding dependent claim 12, Esteller teaches, the apparatus of claim 10, wherein:

different values for n are to be associated with different event classes. (see col. 31, Window Length Selection, lines 52-56)

Regarding dependent claim 13, Esteller teaches, the apparatus of claim 11, wherein:

different values for n are to be associated with different event classes. (see col. 31, Window Length Selection, lines 52-56)

Regarding dependent claim 14, Esteller teaches, the apparatus of claim 1, further comprising:

a signal input for the input of a physiological signal (see Abstract, lines 4-10); and

a transformation unit (see Figure 3, element 200) which is connected to the signal input for receiving the physiological signal and which is adapted to implement a transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation operation (see col. 18, lines 41-60 and also see col. 20, lines 26-36); wherein the probabilistic neural network is connected to the transformation unit for receiving the values as the value set.(see Figure 1, element 200)

Regarding dependent claim 15, Esteller teaches, the apparatus of claim 14, wherein:

the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets. (see col. 28, lines 21-44)

3. **Claim 9 is rejected** under 35 U.S.C. 103(a) as being unpatentable over **Esteller**, in view of **Mouchawar** and further in view of Gray et al. (U.S. Patent No. **6,144,879** and referred to as **Gray** hereinafter).

Regarding dependent claim 9,

Esteller teaches an apparatus for the classification of physiological events on the basis of physiological signals (see Abstract, lines 4-10) as cited above.

Mouchawar teaches cardiac events on the basis of cardiac signals, IEGM (intracardial electrograms) are known to be physiological signals [Arterial blood pressure is a physiologic parameter that is known to be representative of hemodynamic performance, Col. 4, lines 13 – 15; the cardiac wall displacement signals correlate to known hemodynamic indicators, and are shown to be strongly suggestive of hemodynamic performance, Abstract], for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18]

Gray teaches a medical device is in the form of a cardiac pacemaker or defibrillator [Abstract, Fig. 4, and Fig. 8], for the purpose of constituting a pulse generator [Col. 1, lines 23 – 26].

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of **Esteller** to include "a medical device is in the form of a cardiac pacemaker or defibrillator", for the purpose of constituting a pulse generator [Col. 1, lines 23 – 26].

4. **Claim 16 is rejected** under 35 U.S.C. 103(a) as being unpatentable over **Esteller**, in view of **Mouchawar** and further in view of Christopher P. Townsend et al. (U.S. PG Pub. No. **2005/0126026** and referred to as **Townsend** hereinafter).

Regarding dependent claim 16,

Esteller teaches an apparatus for the classification of physiological events on the basis of physiological signals (see Abstract, lines 4-10) as cited above.

Mouchawar teaches cardiac events on the basis of cardiac signals, IEGM (intracardial electrograms) are known to be physiological signals [Arterial blood pressure is a physiologic parameter that is known to be representative of hemodynamic performance, Col. 4, lines 13 – 15; the cardiac wall displacement signals correlate to known hemodynamic indicators, and are shown to be strongly suggestive of hemodynamic performance, Abstract], for the purpose of deriving cardiac wall displacement from a cardiac wall motion sensor signal and for using cardiac wall displacement as a hemodynamic indicator. [Col. 1, lines 16 – 18]

Townsend teaches an anti-aliasing filter adapted to suppress signal components occur at frequencies above half a sampling rate [Hardware low pass filter 24 also serves as an antialiasing filter, which is a filter that limits the frequency content of the sensor signal to a maximum frequency that is half the sample rate (100 Hz), see Fig. 2e, [0061]] for the purpose of providing additional noise reduction [0061].

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of **Esteller** to include "an anti-aliasing filter adapted to suppress signal components occur at frequencies above half a sampling rate", for the purpose of providing additional noise reduction [0061].

Response to Amendment

Claim Rejections - 35 USC § 102 & 103

5. Applicant's efforts to raise further limitations to modify the claims which can not be found in **Esteller** and **Grey** reference, yet, the examiner found further references teaching the new cited limitation which can be combined with **Esteller** and **Grey** reference to form a new set of rejections listed above in current office action. Forth 102(e) rejections have been withdrawn.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sunray Chang who may be reached Monday through Friday, between 8:00 a.m. and 5:00 p.m. EST. via telephone number (571) 272-3682 or facsimile transmission (571) 273-3682 or email sunray.chang@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Knight can be reached on (571) 272-3687.

The official facsimile transmission number for the organization where this application or proceeding is assigned is (571) 273-8300.

Anthony Knight
Supervisory Primary Examiner
Group Art Unit 2121
Technology Center 2100
U.S. Patent and Trademark Office

May 11, 2007

DAVID VINCENT 5/14/07
SUPERVISORY PATENT EXAMINER